DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

THE MANUFACTURE OF PRODUCTS PREPARED BY CYTAPHERESIS

Form Approved; OMB No. 0910-0124
Expiration Date: November 31, 2001.
See Reverse of Part 3 for OMB statement.

DATE SUBMITTED

NOTE: This report is mandated by Section 351 of the Public Health Service Act; the Federal Food, Drug and Cosmetic Act, Section 502 and Title 21, CFR Part 600. No license may be granted unless this completed application form has been received.

1. MANUFACTURER'S NAME, ADDRESS AND ZIP CODE	TELEPHONE NO. *(Include Area Code)*
2. ESTABLISHMENT NAME, ADDRESS AND ZIP CODE	TELEPHONE NO. *(Include Area Code)*

3. TYPE OF APPLICATION ☐ ORIGINAL ☐ AMENDED

4. LIST THE PRODUCTS PREPARED AND THE EQUIPMENT *(Manufacture, model)* THAT IS USED FOR THE PREPARATION OF EACH.

5. ESTIMATE THE NUMBER OF EACH PROCEDURE PERFORMED ANNUALLY.

6. LIST THE NAME AND QUALIFICATIONS OF THE INDIVIDUAL DIRECTLY RESPONSIBLE FOR THESE PROCEDURES.

7. LIST THE DONORS SUITABILITY CRITERIA INCLUDING CELL COUNT AND DONATION FREQUENCY LIMITS.

8. LIST THE QUALITY CONTROL PROCEDURES PERFORMED. ATTACH COPY OF QUALITY CONTROL

9. LIST THE DATING PERIOD ASSIGNED TO EACH PRODUCT.

CERTIFICATION

I certify that there is documentation in the records which supports that, for each unit of the products covered in this application, all critical manufacturing steps have been performed in accordance with current Federal Regulations and that the responsible individual has signed the pertinent manufacturing records on the day of manufacture.

I also certify that all statements made in this application are true and complete to the best of my knowledge and ability. I am familiar with the pertinent Sections of Part 600-640 of Title 21, Code of Federal Regulations and am aware of my responsibilities described therein.

WARNING: A willfully false certification is a criminal offense. U.S. Code, Title 18, Section 1001.

TYPED NAME OF RESPONSIBLE HEAD	SIGNATURE	DATE

ATTACHMENT

A. Attach you SOP or reference published methods if a recognized procedure is used.
B. Attach 3 copies of labeling *(including all overlays and circular* with directions for use)* for all products. Labels should be submitted on Form FDA 2567, "Transmittal of Labels and Circulars," in triplicate and may be mock-ups or printer's proofs.
C. Quality control procedures.
*If AABB/ARC circular is used without modification, submit one copy only.

Paperwork Reduction Act Statement:
A federal agency may not conduct or sponsor and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average .66 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to:

DHHS/PHS/FDA/Director
Center for Biologic Evaluation and Research (0910-0124)
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